

REMARKS

The Examiner has requested that the Applicants elect one of the following two inventions, which the Examiner contends are independent or distinct.

- I. Claims 1-15 are drawn to a composition; and
- II. Claims 16-33 are drawn to a method of treatment.

Applicants respectfully request that this restriction requirement be withdrawn. Claims 1-15 relate to a composition utilizing viable nonepidermal epithelial cells and an absorbable substance capable of maintaining the viability of said cells, which is used for the treatment or prevention of adhesions. Claims 16-33 define the method of treating or preventing adhesions using those compositions. Any prior search with regard to the composition claims would inevitably have to cover in large measure the patent classes which would be relevant to the method of treatment claims, since the method of treatment uses those very compositions. Since the scope of the search on the two sets of claims would be overlapping to a very large degree, to examine those two sets of claims together (even assuming arguendo, that they do represent two separate inventions) should not be burdensome to the Examiner. MPEP § 803 indicates that claims should not be subject to a restriction requirement if the Examiner can examine them together without undue burden. Since the examination of all the claims in this case together would not place an undue burden on the Examiner, they should all be considered together and the restriction requirement should be withdrawn..

In the event that the restriction requirement is not withdrawn, Applicants elect Group II for prosecution in this application. Further, Applicants affirm the species (i.e., the abdomen, and

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a glue, adhesive or sealant) made during the September 28, 2006 telephone conversation with the Examiner.

Claims 20, 28, 29, and 33-36 remain in the present application. Claims 1-15, the composition claims, have been canceled in an effort to expedite prosecution of the present application. Claim 21 has been amended to focus on a preferred embodiment which is a method of treating or preventing adhesions utilizing viable epithelial cells together with an absorbable protein, such as a fibrin glue. In an effort to focus on this embodiment, claims 16-20, 22-27, and 30-32 have been canceled, claims 28, 29 and 33 have been amended, and claims 34-36 have been added. No new matter has been added, and there is antecedent basis in the application to support both the amendments to the claims and the new claims added herein.

As indicated above, claims in the present application now define a preferred invention of the present invention wherein viable epithelial cells and an absorbable protein (such as fibrin glue) are placed on the injured area (either in a pre-mixed state or separately). Based on the claim, the cells and protein must be placed directly onto the surface of the injured area; intermediate structures, such as scaffolds, are not utilized in the claimed method.

The Examiner has rejected claims 16-33, under 35 USC § 103(a), contending that they are unpatentable over WO 96/22115 (hereinafter “WO ‘115”) in view of US Patent 6,692,738 (hereinafter “McLaughlin et al.”). The Examiner contends that WO ‘115 teaches the prevention of adhesion formation by application of a composition comprising a sheet-like material of cross-linked fiber in combination with a fibrin glue. The Examiner further contends that McLaughlin et al. teaches the seeding of cells, such as fibroblasts, which express therapeutic agents in a matrix. The Examiner goes on to reason that it would have been obvious for one of ordinary skill

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in the art to utilize cells such as fibroblasts in the method described in WO ‘115. In view of the amendments made herein, the Applicants respectfully traverse this rejection.

By specifying that the epithelial cells and protein are deposited directly onto the injured area, the method defined by the claims of the present application clearly distinguishes over the art cited by the Examiner. Neither the McLaughlin et al. patent nor WO ‘115 teaches applying cells directly onto the surface of a wound site. McLaughlin et al. teaches the building of a “scaffolding” to form new tissue, the cells are not deposited directly onto the wound site. Rather, in McLaughlin et al., the scaffolding holds the cell in a matrix to grow new tissue within the matrix as it is absorbed slowly and allows revascularization. Cells are injected into the scaffolding but are not intended to be deposited directly onto the surface of the wound. WO ‘115 is somewhat similar in that regard, requiring the use of barrier materials. WO ‘115 and McLaughlin et al. do not achieve their desired result without the use of sheet-like scaffolding or barrier materials. The application of sheet-like materials in surgery is difficult and requires greater time and skill than applying or spraying a liquid, as proposed by the present claims, directly onto the wound site. Such direct application, as required by the present claims, is not envisioned by either reference cited by the Examiner and, therefore, it is submitted that the present claims are allowable over those references. Accordingly, it is respectfully requested that the rejection under 35 USC § 103(a) be withdrawn.

In light of the foregoing, it is respectfully submitted that the claims of the present application, as amended herein, are in form for allowance. Accordingly, reconsideration and allowance of the claims, as amended herein, are earnestly solicited.

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Respectfully submitted,
John N. Semertzides et al.

by Steven J. Goldstein

Steven J. Goldstein
Registration No. 28,079

FROST BROWN TODD LLC
2200 PNC Center
201 East Fifth Street
Cincinnati, Ohio 45202-4182
Telephone (513) 651-6131

January 26, 2007